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In the Supreme Court of the United States
OCTOBER TERM, 1979

SIDNEY A. DIAMOND, COMMISSIONER OF
PATENTS AND TRADEMARKS, PETITIONER

v.

ANANDA M. CHAKRABARTY

ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF CUSTOMS AND PATENT APPEALS

REPLY BRIEF FOR THE PETITIONER

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Respondent and his Amici contend primarily that it has long been a recognized practice in the Patent Office to grant patents on living organisms; that this Court should, as a matter of policy, interpret the Act to include living things, leaving it to Congress to exclude them expressly from the statute if it deems that desirable; and that the plain language of 35 U.S.C. 101 includes living things, and the legislative history

(1)

of the Plant Patent and Plant Variety Protection Acts does not suggest otherwise.¹ None of the contentions has merit.

1. In contrast to the position of amicus American Patent Law Association (Br. 23), Chakrabarty argues that “[p]revious Patent Office policy has been to grant patents on living things, and specifically on bacteria” (Resp. Br. 12; 12-25). He is wrong.

As proof of his assertion, respondent produces a list of 68 “patents claiming living subject matter”

¹ Amici Hood, *et al.* contend in addition that the case should be remanded for further consideration of whether the bacterium here is a product of nature, or, in the alternative, that the writ of certiorari should be dismissed as improvidently granted (Hood Br. 10-12). They claim that the patent examiner rejected the application solely on a “product of nature” rationale and that when the Board overturned this ground and rejected the claims because drawn to nonstatutory subject matter of living things, it violated a governing regulation (37 C.F.R. 1.196(d)) by not returning the application to the examiner for amendment (Hood Br. 10 & n.8). Amici are doubly wrong. The examiner based his rejection on two separate grounds: that the claims were to a product of nature, and that the claims were “not within the classes of subject matter patentable under section 101” (Pet. App. 166a). The Board reversed the first ground but affirmed the second. Moreover, even if “product of nature” were the only ground for the examiner’s rejection, the Board still followed its regulation. The regulation permits the applicant to “waive such reconsideration before the primary examiner and have the case reconsidered by the Board of Appeals upon the same record before them.” 37 C.F.R. 1.196(b). Chakrabarty chose this course and sought reconsideration before the Board (Pet. App. 168a-169a; Ct. of App. Rec. 97-113), thus waiving whatever rights he may have had to reconsideration before the examiner. There is thus no procedural defect in this case, and no basis for a remand or for dismissal of the writ as improvidently granted.

issued by the Patent Office from 1873 to the present (Resp. Br. 18; Resp. Br. App. 16a-18a). Whatever 68 such patents issued by examiners without review in more than a century might prove in the way of administrative practice, Chakrabarty’s list is vastly inflated. We have examined each of the listed patents, and only three of the 68 clearly claim a novel, living organism itself.² The great majority of these 68 patents identify known, pre-existing organisms generally incidental to a process, combination, medium, or inanimate component.³ Moreover, since this handful of patents was issued without review by the Board of Appeals or the Commissioner, it is particularly poor proof of agency practice.⁴

² These three patents, all issued since 1967, bear the numbers: 3,923,601; 3,856,574; and 3,864,117. Six more, all issued since 1966, claim newly discovered microorganisms in an old medium, and thus involve a combination of a microorganism and non-living material (but cf. *Parker v. Flook*, 437 U.S. 584 (1978); Pet. 6 n.6). These are numbers: 3,228,840; 3,651,215; 3,683,068; 4,003,789; 4,070,453; and 4,166,112.

In addition, there are eight other patents of similar vintage which arguably claim a new living organism in combination with non-living material: 3,192,116; 3,632,747; 3,642,982; 3,709,782; 3,984,575; 4,138,498; 3,683,550; 3,935,066.

³ A summary of the early patents cited by respondent is attached as the Appendix, *infra*.

⁴ Contrary to respondent’s assertion (Br. 19-20), the Board of Appeals in *Ex parte Farr* (Resp. Br. App. 6a-8a) did not rule that organisms in themselves are statutory subject matter. It had no occasion to do so, for Farr never claimed a novel strain of bacteria. Rather, he told the Board that the essence of his multi-step invention was “the use of additional ingredi-

Respondent's further contention (Resp. Br. 12-16) that the patents invalidated by this Court in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), and *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931), were on living things, rests on a misconception of the claims in those cases. The Court never considered the patentability of living things in those cases—and for very good reason. The Patent Office had not granted patents on living things because, unlike Chakrabarty, the inventors had made

ents, plus the concentration of the bacteria and the freezing" of his mixture (Br. before Bd. of App. 8).

That the Patent Office has a subclassification (No. 243) for "Microorganism Per Se" is not remarkable (cf. Resp. Br. 16-17). The category, established in 1979 mainly to conform to a uniform international convention proposed by the World Intellectual Property Organization, shows that, as everyone agrees, on rare occasions examiners have granted patents on specific living things. The failure of the Manual of Patent Examining Procedures to list living things in a group of examples of non-statutory subject matter (Resp. Br. 17-18) is not significant. The list claims no more than to provide some "examples" of non-patentable matter culled from "decisions." It omits non-patentable items such as algorithms. See *Gottschalk v. Benson*, 409 U.S. 63 (1972).

Finally, the 1959 letter from Commissioner Watson to Senator O'Mahoney (Resp. Br. 23) does not advance Chakrabarty's cause. In that letter, the Commissioner noted that patents are granted "on cultures and pharmaceuticals." S. Rep. No. 932, 86th Cong., 1st Sess. 7 (1959). Since no patents had yet been granted on new organisms per se (see note 2, *supra*), the Commissioner presumably referred to process patents where the use of "cultures" to produce "pharmaceuticals" was common or to patents such as those in the Appendix, *infra*.

no such claim.⁶ To be sure, the patents involved living things, but such involvement, as in a process patent (see Pet. Br. 38), is not necessarily an obstacle to patentability, because it is not a claim to the living thing itself. What makes Chakrabarty's claim significantly different and important is that he has claimed a specific organism itself.

2. Respondent (Br. 25-31) and his Amici (American Society for Microbiology Br. 7-11; Pharmaceutical Mfgrs. Assoc. Br. 10-20; Genentech Br. 6-20; Pieczenik Br.) suggest that it is desirable, as a policy matter, to issue patents for microorganisms, and that accordingly this Court should read Section 101 as permitting the issuance of such patents, leaving to Congress the option of specifically excluding living organisms if it wishes to do so. Even if the desirability of permitting such patents were clear, this analysis is inconsistent with the Court's approach to Section 101, as we discuss in our main brief (at 12). But the question of whether, and to what extent, living things should be patentable is far from clear, as the briefs

⁶ In *Funk Brothers* the claim was to the discovery that "well-recognized" strains of bacteria could be mixed together so that they did not inhibit each other in fixing nitrogen in plant roots. *Funk Brothers*, *supra*, 333 U.S. at 129 n.3. See Patent No. 2,200,532 (May 14, 1940). The inventor did not isolate or create any new organism. *Ibid.*

In *Brogdex* the inventors discovered that borax inhibits the growth of blue mold on orange skin. They claimed a process for impregnating the orange with borax and the resulting combination product of orange and borax. There was no claim to a new variety of orange.

of Amici themselves demonstrate (see, e.g., Pieczenik Br.; Genentech Br. 15-16).⁶

Respondent and Amici suggest that concerns over the risks of genetic engineering, like that involved in Chakrabarty's invention on the one hand and recombinant DNA research on the other, are exaggerated (e.g., Resp. Br. 25-27; Genentech Br. 10; Pharmaceutical Mfgrs. Assoc. Br. 15-18). But Chakrabarty himself has recently recognized those hazards. See A. Chakrabarty & J. Brown, "Microbial Genetic Engineering By Natural Plasmid Transfer—Some Representative Benefits and Biohazards", reprinted in *Genetic Engineering* 185-193 (Chakrabarty ed. 1978). Thus, Chakrabarty frankly acknowledged that the

⁶ Amicus Pieczenik suggests that there is not always a clear distinction between the living and the non-living. In the present case and in many others, however, there can be no dispute on that question—the microorganisms resulting from Chakrabarty's work are alive. When and if closer cases arise, it will be incumbent on the courts or Congress to develop appropriate standards to decide them—just as courts and legislatures have recently found it necessary to consider the effects on the definitions of homicide and death of new scientific knowledge and practices.

Genentech notes that the Patent Office has suspended the examination of patent applications on plasmids, and suggests that this case would be an appropriate vehicle to decide whether plasmids are patentable (Genentech Br. 16-17). We do not agree. Examination of the approximately 16 pending applications for patents on plasmids or genes was suspended until the instant case is finally decided because almost all of these applications also claim a microorganism per se. The Patent Office has taken no position on the patentability of plasmids or genes, an issue not now before the Court, and this Court should not act until the Patent Office has had an opportunity to study and decide the question.

hazard resulting from a possible "change of the local ecological balance due to the massive seeding with the multiplasmid organism that might be required to rapidly digest the oil spill" is "less simply disposed of" than other claimed hazards (*id.* at 190). He cautioned that "tests for acute toxicity" should be done before there was any large-scale manufacture of the multiplasmid microorganism. *Ibid.*⁷ Moreover, while the controversy over the hazards involved in recombinant DNA may not be as intense as it was two or three years ago, it is still cause for concern. See *Recombinant DNA Research; Proposed Actions Under Guidelines*, 44 Fed. Reg. 69234, 69241-69245 (1979); Krimsky & Ozonoff, *Recombinant DNA Research: The Scope and Limits of Regulation*, 69 Am. J. Pub. Health 1252, 1257 (1979).⁸

⁷ Chakrabarty also expressed some concern about the hazards involved in the development of hybrid strains of *E. coli* using his plasmid-transfer technique (*id.* at 192). He destroyed one such genetically-engineered organism because he anticipated it might have had an adverse effect if introduced into the human intestine. Wade, *Dicing with Nature: Three Narrow Escapes*, 195 Science 378 (1977).

⁸ Amicus Genentech argues (Br. 10) that "worries about the dangers of genetic engineering have all but disappeared" quoting a Harvard professor, Dr. Walter Gilbert. See "Glamour Stock" Could Help Cancer Patients, Los Angeles Times, Jan. 21, 1980, Part I, at 3, 16. Dr. Gilbert helped form, and is chairman of the scientific board of, Biogen S.A., a Swiss company that is attempting to exploit the commercial possibilities of genetic engineering (*ibid.*). He is thus hardly an impartial observer in the debate over the biohazards associated with genetic engineering developments.

In any event, there is still much controversy over the question of whether patents should be granted on organisms that result from genetic engineering (see Pet. Br. 20; Krimsky & Ozonoff, *supra*, 69 Am. J. Pub. Health at 1253). The Amici favoring respondent stress the beneficial results of genetic engineering research and the importance of encouraging that research through the availability of patent protection.⁹ But these policy arguments should be addressed to Congress, not this Court (see Pet. Br. 14-15, 20).

3. Respondents (Br. 37-42) and Amici (Hood Br. 18-19; Genentech Br. 22; Regents Br. 10-13; N.Y. Patent Law Association Br. 8-15) contend that Chakrabarty's invention is within the statutory language defining patentable subject matter since a living organism is either a "manufacture" or "composition of matter" (35 U.S.C. 101).

But Section 101 does not stand alone. The relevant statutory text includes both the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970. The terms of Section 101 are thus shaped by these Acts, and under traditional canons of statutory construction, the entire statutory scheme provides strong evidence that Section 101's general subject matter definition does not include living things. See Pet. Br. 21-23.

⁹ The suggestion that the inability to patent a living organism will seriously impede the development of the technology of genetic engineering overlooks the availability in appropriate circumstances of patents on the *process* by which the new organism is developed.

In any event, this Court has rejected a purely literalistic reading of Section 101.¹⁰ *Parker v. Flook*, *supra*, 437 U.S. at 588-589. See *In re Arzberger*, 112 F.2d 834, 847 (C.C.P.A. 1940). Nor does the ordinary understanding of these terms necessarily comprehend living organisms. Common parlance simply does not tell us whether, in creating a hybrid organism with changed characteristics from those of pre-existing organisms, Chakrabarty did or did not "invent or discover" a new "manufacture" or "composition of matter."

Moreover, other familiar terms and concepts of the patent law are not easily adapted to the patenting of living microorganisms that reproduce themselves. The microorganisms themselves presumably would not infringe the patent by reproducing (and thereby manufacturing themselves) without a license. And a human being who himself becomes infected, or whose plant or animal (or whose food, liquid, etc.) becomes infected, presumably also would not become an infringer merely by providing the medium in which the microorganisms propagate (at least if he does so unintentionally and takes reasonable measures to curb the growth of the infection—and does not use the microorganisms in any way). But the very fact that living organisms may reproduce in ways and places uncontrolled by the patentee or his licensees,

¹⁰ Although Amici Regents of the University of California argue that the plain language of Section 101 covers Chakrabarty's invention, they forcefully point out that the CCPA has repeatedly refused to accept this Court's interpretation of that Section and that the CCPA's rationale in this case is inconsistent with this Court's decisions (Br. 24-27).

and perhaps in profusion (see J.A. 62, 77), suggests that patent grants on the organisms themselves would be unprecedented in scope.¹¹

4. We have explained in our main brief why the Plant Patent Act cannot reasonably be considered to be based on the belief that plants were unpatentable under the general patent laws because they were products of nature (Pet. Br. 33-36). Significantly, Congress distinguished between plants found in nature and those created by plant hybridizers like Luther Burbank, but nevertheless concluded that a new statutory provision was necessary to protect the latter, which were clearly *not* products of nature. Respondent maintains, nonetheless, that, with respect to Burbank's work, "it apparently was concluded that insufficient change to the plant was caused by man (rather than nature) to make the new plant a manufacture" (Resp. Br. 44). No authority is cited for this proposition. Respondent simply suggests that, because the genetics of hybridization were not fully understood in 1930 and because, when a cross was made, the resulting hybrid was not predictable, the hybrid was somehow a product of nature (*ibid.*). But it has never been a requirement for patentability under the patent law that an inventor anticipate, or fully understand, his results. See, *e.g.*, *Eibel Process*

¹¹ Certainly the offspring of an organism that sexually or asexually reproduces itself are not "made" by man, in the ordinary sense of that term. Compare 35 U.S.C. 154 with 35 U.S.C. 163.

Co. v. Minnesota & Ontario Paper Co., 261 U.S. 45, 62-65 (1923).

Moreover, the plant hybridizer of that day as much obtained "exactly what he set out to obtain" (Resp. Br. 45) as did Chakrabarty.¹² We have already referred to Burbank's selection of certain varieties for crosses (Pet. Br. 33-34 n.40). Similarly, Thomas Edison (a founder of the General Electric Company, the assignee of Chakrabarty's patent application) developed in 1929 a new, hybrid variety of goldenrod from which he extracted rubber. The new plant was created by Edison from the deliberate, calculated cross of two known species. See B. Vanderbilt, *Thomas Edison, Chemist* 94, 285-295, 320 (1971). Yet, as far as can be determined, Edison, a prolific patentee, never sought a patent on his new hybrid. Instead, in a communication reprinted in the reports of the congressional committees, he urged passage of the Plant Patent Act to afford patent protection to the work of plant breeders like himself. H.R. Rep. No. 1129, 71st Cong., 2d Sess. 3 (1930); S. Rep. No. 315, 71st Cong., 2d Sess. 3 (1930).

¹² The course of Chakrabarty's own research with plasmids demonstrates that he engaged in considerable trial and error experimentation before he obtained the hybrid microorganism he now seeks to patent. See A. Chakrabarty & J. Brown, *supra*, at 188; Chakrabarty, *Genetic Fusion of Incompatible Plasmids in Pseudomonas*, 70 Proc. Nat'l Acad. Sci. 1641, 1642 (1973); Chakrabarty, *Genetic Regulation of Octane Dissimilation Plasmid in Pseudomonas*, 70 Proc. Nat'l Acad. Sci. 1137, 1138-1139 (1973).

CONCLUSION

For the foregoing reasons, and those stated in our opening brief, the judgment of the Court of Customs and Patent Appeals should be reversed.

Respectfully submitted.

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APPENDIX

PATENTEE	DATE	SPECIFICATION, AMENDMENTS AND ABSTRACT; NATURE OF CLAIMS
141,072 Pasteur	May 9, 1873	Improvement in the Manufacture of Beer and Yeast Improved Process for obtaining pure yeast free from contami- nating germs or disease, employ- ing distinctive apparatus. Claims are for (1) method of obtaining pure yeast; (2) "yeast free from organic germs or disease." No particular strain of yeast claimed.
899,155 Coates	September 22, 1908	Fertilizer Process for sterilizing dried ma- terials, such as bone phosphate, dried slack lime and potash salts, and then inoculating it with a pure culture of a beneficial bac- teria. The novelty resides in the idea of using a "practically dry fertilizing material of such na- ture as will not injuriously affect the life of the micro- organism." Claims are for the dried fertilizer in combina- tion with a micro-organism. No particular micro-organism claimed.
952,418 Collett et al.	March 15, 1910	Dietetic Chocolate and Cocoa Process for preparing chocolate or cocoa. The novelty resides in the idea of putting a "fer- ment" compound of micro- organisms or enzymes into fin- ished cocoa and then <i>drying</i> it, instead of then <i>heating</i> it as in prior processes. See amendment of Nov. 23, 1909. Claims are for the process and for the product of the cocoa and ferments com- bined. No particular micro- organism claimed.

PATENTEE
DATE

SPECIFICATION,
AMENDMENTS AND
ABSTRACT; NATURE OF
CLAIMS

1,099,121 Earp-Thomas June 2, 1914	Means for Distributing Soil Bacteria	Substantially nitrogen-free soil also freed of weeds, seeds and harmful organisms but containing available carbonaceous matter and artificially inoculated with "beneficial soil bacteria." The novelty resides in the idea of <i>combining</i> sterile soil with the beneficial bacteria, as compared to prior methods that used soil that had not been first freed of harmful bacteria. See amendment of Dec. 12, 1912. No particular strain of bacteria claimed.
1,120,330 Odle December 8, 1914	Medicated Food Product	A process for producing a palatable and readily-stored medium for introducing beneficial bacteria into the human digestive tract. See September 12, 1914 amendment. A "suitably concentrated culture of the desired [lactic acid] bacilli," is combined with cream, and then frozen. The patent claims a food product "comprising a frozen confection containing a culture of lactic acid bacilli * * *." No new bacterium claimed.
1,178,941 Palma April 11, 1916	Preparation for Infecting Vermin With Disease	"[M]ethod of and a preparation for destroying vermin by administration of nitrates in conjunction with administration of pathogenic bacteria." The novelty resides in the use of nitrates in combination with the bacteria to ensure the effectiveness of the bacteria. See April 2, 1914 response of Palma. No particular bacteria claimed.

PATENTEE
DATE

SPECIFICATION,
AMENDMENTS AND
ABSTRACT; NATURE OF
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1,260,899 Harris, et al. March 26, 1918	Process for Compounding Germs With An Enveloping Protective Medium	Process for administering "living germs" by mouth and preserving "their vitality during their passage through the stomach." The novelty resides in the process of reducing the germs to "a dormant state" and then enveloping them "with an air and moisture excluding [inert] substance" such as petrolatum. No new strain of bacteria claimed.
1,442,239 Stoltz January 16, 1923	Composition of Matter	A fertilizer, consisting of "a mixture of finely ground marble or limestone, phosphate rock and organic humus mixed together in about equal parts by weight, and impregnated with nitrifying bacteria." The novelty apparently resides in the unique combination of materials. No particular bacterium claimed.
1,457,097 Whitmore May 29, 1923	Vaccine and Method of Preparing Same	Both a method for preparing a vaccine and the vaccine prepared using the method. The novelty resides in the method of "embalming" living bacteria by "attenuating and sedimenting" the living organism, drying it, and finally grinding it in oil to "discrete or separate and individually coat with oil the cells or organism". See Whitmore's response of April 2, 1920. One claim (#9) specifies a vaccine composed of "living anthrax bacilli suitably prepared, discreted, and suspended in neutral, sterile vegetable oil" but there is no claim to any novel microorganism.

PATENTEE
DATE

SPECIFICATION,
AMENDMENTS AND
ABSTRACT; NATURE OF
CLAIMS

1,540,951 Reichel June 9, 1925	Process of Growing Lactobacilli and the Product	"[P]rocess of growing lactobacilli * * * in a culture medium other than milk or whey with the object of obtaining an increased number of bacilli in the medium, and harvesting the growth in a compact ingesting volume or mass." The novelty is in the idea of using a culture medium other than the digesting milk or casein previously used to grow the lactobacilli. No particular strain of bacteria claimed.
1,758,937 Earp-Thomas May 20, 1930	Lactobacteria Product	"[F]luid oil product containing viable lactobacteria, suitable for implantation in the intestinal tract." The novelty resides in the use of an emulsion of a suitable oil and a suitable emulsifying agent that serves to prevent the culture from settling out of the carrier. No particular strain of bacteria claimed.